

**Synthes Spine 510(k) Premarket Notification
Modified USS Fracture System**

JUN - 4 2001

3.0 Summary of Safety and Effectiveness Information

SPONSOR: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Jonathan Gilbert

DEVICE NAME: Modified USS Fracture System

CLASSIFICATION: The classification of the Synthes Modified USS Fracture System components is Class II, as per the Code of Federal Regulations, Title 21, Section 888.3070: Pedicle Screw Spinal System. The product code is MNI and MNH. The Panel code is 87.

PREDICATE DEVICE: K963357 – Synthes Universal Modular System

DEVICE DESCRIPTION: The USS Fracture System adds the following new components to the implants described by the predicate device:

- ø 5.0, ø5.2, ø6.2 and ø7.0mm dual core double lead Schanz screws,
- low profile clamps,
- cranial clamps,
- double-threaded ø6.0mm Schanz screws, and
- USS Cross-link Clamp (pre-assembled).

The subject screws are affixed to the spine using previously cleared 6.0mm USS rods and transconnector components.

INTENDED USE: Posterior Components

When used as a posterior pedicle screw fixation system, the Synthes USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes USS is intended for treatment of severe spondylolisthesis (grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous

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INTENDED USE: (continued)

bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system, the Synthes USS is intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

- / The Click'X and USS VAS components of the Synthes USS, when used as a posterior pedicle screw fixation system, are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, spinal tumor and failed previous fusion (pseudoarthrosis).
- / In addition, the Click'X and USS VAS components of the Synthes USS are intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

In addition, when used with 3.5/6.0 mm parallel connectors, the Synthes USS can be linked to the CerviFix System.

Anterior Components

The Anterior Components of the USS are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

MATERIAL:

The components are made from either titanium alloy TiAlNb (ASTM F1295) or implant grade stainless steel (ASTM F 138).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2001

Mr. Jonathan Gilbert
Sr. RA Associate
Synthes Spine
1690 Russell road
Paoli, Pennsylvania 19301

Re: K010658

Device Name: Modified USS Fracture System
Regulation Number: 888.3070, 888.3060, 888.3050
Regulatory Class: II
Product Code: MNI, MNH, KWP, and KWQ
Dated: March 5, 2001
Received: March 6, 2001

Dear Mr. Gilbert:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. Jonathan Gilbert

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. M. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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2.0 Indications for Use Statement

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510(k) Number (if known): K010658

Device Name: Modified USS Fracture System

INDICATIONS

Posterior Components

When used as a posterior pedicle screw fixation system, the Synthes USS is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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Indications for Use Statement (continued)

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Anterior Components

The Anterior Components of the USS are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

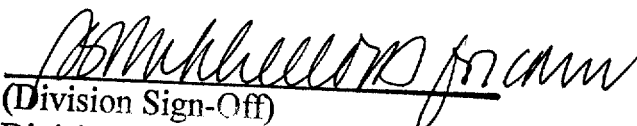
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____


(Division Sign-Off)
Division of General, Restorative
and Neurological Devices
510(k) Number K010658